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March 25, 2005

Mr. Gary M. Jackson
Assistant Administrator for Size Standards
409 Third Street SW
Washington, DC 20416
SENT BY OVERNIGHT EXPRESS MAIL

RE: RIN-3245-ZA02
Advanced Notice of Proposed Rule Making ANPRM; 69 FR 70197

Dear Mr. Jackson:

On December 3, 2004 the Small Business Administration (SBA) announced a revision to its small business size regulations for ownership and control of Small Business Innovation Research (SBIR) program awardees (see Federal Register; Volume 69, No. 232, pp. 70180-70185). Previously SBA had proposed (68 FR 33412 June 4, 2003) to allow a small business owned or controlled by another business to be eligible for SBIR funding.

One of the issues that emerged in response to SBA's proposal was whether small businesses that are majority owned and controlled by venture capital companies (VCCs) should be eligible to receive SBIR grants. The final rule, which was effective January 3, 2005, does not make a distinction between VCCs and other for-profit entities. It allows ownership so long as the parent company and other affiliates together with the small business meet the 500 employee size standard for SBIR eligibility (and so long as the small business is at least 51% owned and controlled by one or more individuals who are U.S. citizens or permanent residents or another for-profit business concern that itself meets the 51% U.S. citizenship or resident requirement). The VCC issue is discussed at 69 FR pages 70201-202.

We recommend that the SBA keep the definition of ownership and control that was in the Final Rule, and we strongly recommend that VC- funded companies continue to be eligible for SBIR funding.

Universities often license their technologies to small start-up, research-intensive companies where SBIR funding can help reduce private investment risk and help prepare early-stage technologies for market. Many small, emerging high tech and life science companies look both to venture capital and SBIR as critical elements for their development and ultimate success. If VC-owned small businesses are unable to participate in the SBIR program, this will eliminate a valuable tool for these early-stage technology driven businesses and will have a significant negative impact on both the creation of small businesses in the U.S. and effective university-to-industry technology transfer.

There is a critical need for early-stage capital investment for technology-intensive small companies. For example, in biotechnology it is estimated that it takes $600 – 800+ Million and 12 years to develop a new compound into a pharmaceutical product, conduct clinical testing, and gain the approved of the Food and Drug Administration to market the drug. [See the Tufts Center for the Study of Drug Development for a discussion of costs: http://csdd.tufts.edu/Research/Agenda.asp]. Without Venture Capital, many important therapies may never be developed, since most of the new drug development occurs in small, research-intensive companies before it is transferred to larger, fully-integrated pharmaceutical companies for final marketing and sale.

Similarly, in early stage information technology business, SBIR grants provide essential early-stage support for feasibility and proof of concept testing.

We urge the SBA to keep the current definition of ownership and control that was codified in the Final Rule, whereby VC-owned small businesses can continue to compete for SBIR funding.

Sincerely,

James A. Sev

James Severson, Ph.D.
Vice Provost, Intellectual Property and Technology Transfer

JAS:cmh